Trinity Health Of New England | Johnson Memorial Hospital

Approved
7/2/18
SHN

June 19, 2018

Ms. Susan H. Newton, R.N., B.S.
Supervising Nurse Consultant
Facility Licensing and Investigations Section
410 Capitol Avenue, MS #12HSR
P.O. Box 340308
Hartford, CT 06134

Dear Ms. Newton:

Pursuant to your letter dated June 11, 2018, attached please find Johnson Memorial Hospital's Corrective Action Plan for unannounced visits made to Johnson Memorial Hospital concluding on April 3, 2018 for the purpose of conducting multiple investigations, in follow-up to a violations letter dated March 1, 2016, a licensure inspection and a certification survey.

Should you have any questions or require additional information, please do not hesitate to contact me directly at (860) 684-8101.

Thank you.

Sincerely,
Stuart E. Rosenberg, M.B.A.
President

Enclosures

DATES OF VISIT: December 18, 19, 20, 21, 2017 and February 14 and April 3, 2018

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical plant (1) and/or (4) and/or (b) Administration (2) and/or (i) General (6).

1. *Based on a tour of the hospital, review of hospital policies, hospital documentation and staff interviews, the hospital failed to ensure that patients on the psychiatric unit were maintained in such a manner as to promote care in a safe setting when multiple ligature points were identified. The findings include:

   On 12/19/17 at 11:00 AM and various times throughout the day, during tour of the 2nd floor adult psychiatric unit along with the Director of Facilities, and the Nurse Manager the following was observed:

   a. Sleeping room numbers 27, 28, 29 and 30 had night lights and thermostats that were identified on a risk based assessment dated 10/2017 conducted by a contractor for the hospital. The assessment identified these as ligature risks and the facility was in the process of removing these ligature risks as part of a mitigation plan following the October 2017 assessment but had not completed mitigation of all the identified hazards prior to the survey. During the survey on 12/19/17, the Life Safety Code Surveyor was able to demonstrate that one of the night lights could bear the load of a person. There was no additional staff supervision and/or environmental rounds conducted while the hospital was removing the identified risks prior to the survey.
   b. The B lounge had a corner TV stand with a DVD player attached to its underside that could be utilized as a ligature point. Lockers with hasps and locks also had not been identified by the risk based assessments as possible ligature points. The TV stand, DVD player and hasp locks all had spaces where an object/item a could be threaded through and used as a liagure point.
   c. The handicap bathroom had faucet controls and a faucet that were ligature risks. The faucet and faucet controls protruded in a manner that would allow an item to be treated around and used as a ligature point.
   d. The affected patient sleeping rooms, the B lounge, hasp locks and the handicap bathroom were accessible to unsupervised patients. Although these hazards were identified by the hospital, the hospital failed to conduct environmental rounds to ensure the safety of the patients. The hasp locks had spaces where an object/item acould be threaded through and used as a ligature point.
   e. Review of clinical records identified a patient census of 14 with 9 of the 14 patients admitted with suicidal ideations. On 12/19/17, the clinical records of Patients #25 through #38 were reviewed. Psychiatrist assessments and every-shift nursing assessments of each patient's suicidality and self-harm risk were completed and identified that no patients currently admitted to the psychiatric unit were actively suicidal or at risk for self-harm. Care plans were updated daily to include each patient's safety risks. All 14 patients were on routine 15-minute observations. Two patients were on additional 5-minute checks; 1 for exhibiting elopement behaviors and 1 who was a new admission in the process of being assessed.

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THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The hospital developed a plan to mitigate the environmental hazards on 12/19/17.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

There were no patients adversely affected by this violation.

Following the exit conference with DPH surveyors, our immediate remediation began with a meeting called by the President with Infection Prevention, Pharmacy, Regulatory, Engineering, Building Services, Director of Nursing, Nurse Managers, and Vice President of Medical Affairs. Conference call between the President and Chairman and Vice Chairman of the Board providing status on findings and corrective action plan.

- In sleeping rooms 27, 28, 29 and 30, the night-lights and thermostats were identified as a ligature risk and were in the process of being addressed during the time of survey. The removal of the night light and modification of the thermostats to eliminate ligature risk was completed on 12/20/2017. The thermostats were then covered by a plastic bubble, removed completely in rooms or rooms placed out of service until remediation. Completed by 2/15/18.
- In lounge B the TV cabinet and DVD player were not in direct view of the nurses' station and could be a ligature risk as well as the lockers with hasps that were identified on the risk assessment. These items were removed on 12/20/2017 and new design for an enclosed TV cabinet and new location for lockers were established on 12/20/2017.
- The faucet in the handicap bathroom was ordered on 10/25/17 and due to be installed the week of 1/15/2018. All future identified ligature risks are monitored by Q15 environmental rounds until such risks are eliminated.
- All ligature risks were removed from the patient sleeping rooms, lounges, as well as lockers with hasps removed on 12/19/2017.
- All new construction for behavioral health areas will pass through the Environment of Care Committee to ensure all designs comply with the standards of care.
- An annual risk assessment, including all patient care areas, is conducted and all risks identified will be immediately monitored until resolve of risk can be met. An outside vendor completed an assessment on 10/26/17.
- Environmental Care Team was educated via electronic system on the module: Assessing and mitigating risk for Suicide and Self Harm. Education completed by 3/15/18.

(2) The date each such corrective measure or change by the institution is effective.

- See above dates.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.

- All risk assessment finding are reported to the EOC committee and Operational Performance Improvement and Safety along with reviewing all work orders until work is complete.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

- Twice yearly EOC rounds with an interdisciplinary team are completed to identify risks.
- All identified EOC risks are placed on Q15 environmental checks.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.

- Manager, Behavioral Health
- Manager, Facilities

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1) and/or (g)(2) and/or (i) General (6) and/or (l) Infection Control (1).

2. *Based on observation, review of facility documentation, contractor reports, email correspondence, interviews, and policy review, the hospital failed to provide the necessary supervision of Pharmacy services to ensure that all primary engineering controls (PEC) were tested in accordance with USP 797 standards and/or policies and/or that highly pathogenic microorganisms noted during environmental testing in the ante and/or chemo rooms were immediately remedied in accordance with USP-797 standards. The findings include:
   a. Review of certification and environmental reports during the period of 2/25/16 through 12/21/17 identified that primary engineering control 1 (LAFW) located in the chemo room, had no viable air and/or surface samples obtained for microbial growth and/or was certified every six months in accordance with USP 797 standards. Observation of the compounding rooms on 2/14/18 at 10 AM noted that the chemo room had one biological safety cabinet in use and an LAFW which had been out of service since 12/2015. Interview with Pharmacy Technician #8 on 2/14/18 at 10:40 AM stated the LAFW is included in the daily cleaning, however, not operational. Interview on 2/14/18 at 11:30 AM with the CEO/President identified that the plan was to remove the LAFW once the Cancer Center pharmacy was operational. Review of the certification policy directed that PEC's would be certified every six months. Review of the environmental monitoring surface sampling policy directed that a sampling plan will be identified that includes each PEC and should be performed at least quarterly. Review of the environmental monitoring air sampling policy directed to sample all PEC's at least every six months.
   b. Review of the action plan form dated 4/14/17 identified that environmental testing of the ante and chemo rooms was completed on 3/22/17 with the final report received on 4/14/17 that noted actionable sterile white hyphae (mold) on the floor and on the cart in the ante room. The ante room floor, cart, and sink was cleaned on 4/14/17 and a terminal clean was conducted on 4/17/17. Re-testing was conducted on 4/19/17 with notification on 4/24/17 that preliminary results show no actionable levels. Review of the environmental report dated 4/19/17 identified an actionable level of gram negative rods were noted in the ante room in the air, a discrepancy noted from the action plan dated 4/24/17. A terminal clean was not conducted until 5/2/17.
   c. Review of the environmental testing report dated 8/3/17 noted actionable sterile white hyphae on the cart in the ante room with appropriate interventions taken. Review of the re-test completed on 8/26/17 identified actionable sterile white hyphae in the air of the

ante room. Review of facility documentation failed to indicate that remediation was taken until a terminal cleaning was done on 9/12/17.

d. Review of the environmental testing report dated 9/21/17 noted actionable levels of mold (Cladosporium) in the air of the ante room. The action plan dated 9/27/17 noted the actionable mold (final genus and species pending) with a plan to consult infection control, requested a work order to replace pipes that were corroded and caulk around the sink, remove faucet aerator, and replace ceiling tiles in the pharmacy. The plan further noted that a terminal clean would be done and re-testing of the ante room once work orders were complete. A terminal clean to address the mold growth was not conducted until 10/10/17.

Review of email correspondence dated 10/18/17 between the pharmacy Manager and Certification Company #1 identified that Staphylococcus, Corynebacterium, and Micrococcus (noted during testing on 9/21/17) were considered human contaminants, the remediation plans dated 10/18/17 failed to address personnel work practices and/or cleaning procedures in accordance with facility policy.

Review of the environmental reports and interview with the Interim Pharmacy Manager on 2/14/17 at 11:10 AM stated she is new in her role and couldn't speak to interventions during the aforementioned periods discussed.

Review of USP 797 standards directed in part, the counts of colony forming units (cfu's) are to be used as a measure of the environmental microbial bioburden. Regardless of the number of cfu's identified in the pharmacy, further corrective actions would be dictated by the identification of microorganisms recovered (at the genus level). Highly pathogenic microorganisms (e.g. Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSP's (compounded sterile products), and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist. Additionally, a cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted, the source shall be eliminated and re-sampling performed.

Review of the Cleaning and Disinfecting policy directed that sterile preparation rooms, including the anterooms and buffer rooms will be cleaned and disinfected at regular intervals and when microbial contamination is known to have been introduced into the compounding area.

Review of certification reports from contracted service #1 identified that the anteroom and buffer rooms were certified on 8/18/16, 2/6/17, and 8/3/17. Review of work orders for corrective maintenance during the period of 1/5/17 through 11/20/17 identified the following:

a. Caulked light in the IV room.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

b. Trap is leaking in the sink located in the ante-room. Installed new trap.
c. Replaced sink in the ante-room.
d. Both pre-filters changed.
e. New sink is leaking. Changed trap.
f. Chipping paint in the IV room, caulking falling off. Repainted/touchup walls around sink, recaulked ceiling grid and recaulked around light fixtures.
g. Faucet is leaking and spraying in the ante-room sink. Installed new eyewash station on faucet.
h. Touched up wall paint, recaulked around door, sealed cracked seam in corner and base of corner sink wall, touched up paint.
i. Cut out old caulk bottom of door frame and resealed. Taped off top of the sink and repainted top and behind sink in corner.
j. Changed two pre-filters.
k. The pipes on the sink are corroded and must be replaced. There should be caulking around the sink. Painted pipes with 2 coats of epoxy paint. Caulked back and rear of stainless sink.
l. Installed new antibacterial laminar flow aerator in the ante-room sink.
m. Installed plastic wall conduit to hide wires that runs to the booster, caulked seams. ecaulked around sink.
n. Remove screws on the wall and fill with caulk and paint.
o. Install mop brackets in the ante-room and the IV room. Drilled out the two holders from the mounting bracket, installed 2 stainless holders with stainless screws in the clean room and ante-room, caulked around brackets, and recaulked the ante-room door frame on the lower left side.

Interview with the CEO on 2/14/18 at 2PM identified that the prior Manager managed the certification process and that it was his understanding that the rooms did not require recertification with minor projects.

Review if USP 797 standards identified certification of each ISO classification area (ISO 8, ISO 7, ISO 5) is within established guidelines and shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.

Based on observation, review of facility documentation, review of contractor reports, interviews, and policy review, the hospital, who compounds sterile pharmaceuticals, failed to maintain a steady state of control in accordance with Federal and/or state laws, and United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations standards. The findings include:

On 02/14/18 at 10:0 AM and at various times throughout the day during a tour of the pharmacy hazardous/non-hazardous chemotherapy mixing room and ante room with the Director of Engineering, Pharmacy Manager and Hospital CEO the following was identified:

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a. The ceiling light fixtures in the Ante Room and Mixing Room were not installed in a fashion promoting the effective cleaning procedures, the light covers were installed upside down not allowing for them to be free from particulates and able to be cleaned.
b. The plastic hangers attached to the wall in the Ante Room were not secured to the wall properly and sealed with caulk to allow for effective cleaning of the area.
c. The flooring at the door area entering the Ante Room were of VCT style tiles and not continuous vinyl flooring as the remaining area not allowing for the effective cleaning of the area.
d. The low air return vents in the Ante Room and Mixing Room had filters which showed dirt/debris on them.
e. The doors to the Ante Room and Mixing Room had brush style floor guards installed on them not promoting a sanitary condition.

Review of the cleaning logs during the period of 1/2/17 through 1/31/18 identified that numerous pharmacy staff performed daily cleaning of the sink, hoods, surfaces (tables, carts, sills, and ledges), chemo hood tray, and floors.

Review of the terminal cleaning logs during the period of 8/1/16 through 2/10/18 identified that contracted service #1 mopped and sanitized ceilings and walls, clean and sanitized designated surfaces including benches, carts, and hoods, doors, glass, and the exterior of equipment located in the ante and chemo rooms.

Interview with Pharmacy Technician (PT) #10 on 2/14/18 at 11:45 AM stated that he intermittently observed the terminal cleaning on 2/8/18 by a contracted service representative. PT#10 further identified that although he was trained how to conduct daily and terminal cleaning when he was hired (7/31/16), there was no training for the observation of contracted company #1.

Interview with the Interim Pharmacy Manager on 2/14/18 at 2:00 PM stated that the facility did not have a policy that directed staff on the monitoring of terminal cleaning by the contracted company. The Interim manager was unable to identify why the aforementioned concerns were not addressed.

Review of the aforementioned concerns and interview with the Regional Infection Control Practitioner on 2/14/18 at 3:00 PM stated that facility staff should have seen the issues and addressed the problems noted.

According to USP 797, Engineering Control Performance Verification- PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits.

Response:

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(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

There were no patients adversely affected by this violation.
Following the exit conference with DPH surveyors, our immediate remediation began with a meeting called by the President with Infection Prevention, Pharmacy, Regulatory, Engineering, Building Services, Director of Nursing, Nurse Managers, and Vice President of Medical Affairs. Conference call between the President and Chairman and Vice Chairman of the Board providing status on findings and corrective action plan.

- Certification of ante room and buffer room will be obtained every 6 months as well as environmental monitoring quarterly and after any work is completed in the pharmacy in accordance with USP 797, the effective date was 2/15/2018.
- Pharmacy Director/Designee will observe any outside company performing work/cleaning/testing in the pharmacy effective 2/15/2018.
- All compounding pharmacy staff have been instructed to clean the exterior of the BSC. Compounding staff have been educated to the cleaning policy revised on 2/15/2018. New staff will be educated upon hire.
- The loose nuts from the safety cabinet were removed and sink in Anteroom was caulked, and terminal cleaning of the room by pharmacy staff was completed on 2/15/2018.
- The remaining items were repaired on3 /9/2018:
    - Door gaskets replaced with washable gaskets, garment hooks caulked, refastened bolts on exhaust hood, light covers flipped to smooth surface and caulked, door sweeps removed, LAFH removed, flooring at the door area entering the ante room was removed and replaced with epoxy flooring, prefilters changed on low air return vents.
- Terminal clean was done on 3/12/2018 by outside vendor.
- Environmental Monitoring and Certification of rooms and hoods were completed on 3/15/2018.
- Environmental monitoring performed on 4/4/2018 and found no actionable results.
- Environmental monitoring results discussed with USP 797 consultant and Infection Prevention on 4/24/2018.
- On May 10, 2018, resumed prepare CSP's labeled with BUD's as indicated in USP 797.

(2) The date each such corrective measure or change by the institution is effective.

- See dates above in item.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.

- Certification of ante room and buffer room will be obtained every 6 months as well as environmental monitoring quarterly and after any work is completed in the pharmacy in accordance with USP 797, the effective date was 2/15/2018.

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THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

- Monthly rounding will be performed by the Director of Facilities and Engineering/Designee and the Interim Pharmacy Manager/Designee monthly to inspect the ante room and buffer room for any deficiencies effective 2/15/2018.
- When any work is required or there is an actionable result obtained from pharmacy testing, pharmacy will immediately implement 12-hour BUD. This will continue until a terminal clean is completed, followed by environmental testing and/or certification. The results will be reviewed by Infectious Disease or Infection Prevention and pharmacy immediately upon receiving results. If actionable items are identified, remediation and corrective action plans will be implemented and documented by the Facility and Pharmacy Director.-Ongoing.
- Twice yearly EOC rounds with an interdisciplinary team will be completed to identify risks. Ongoing.
- All actionable items will be reported to the USP 797 committee and submitted to Operational Performance Improvement and Safety Committee. Effective 3-7-18.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.

- Vice President, Medical Affairs

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical plant (1) and/or (a)(4) and/or (b) Administration (2) and/or (i) General (6).

3. *Based on a revisit of the hospital Behavioral Health Unit, review of policies, facility documentation and interviews with facility management, the hospital failed to ensure that the behavioral health unit including patient sleeping rooms were maintained in such a manner as to promote the safety and well-being of patients within the unit. The findings included the following:
   a. On 02/14/18 at 1:00 PM and at various times throughout the day while on tour of the behavioral health unit with the Director of Engineering and the Hospital CEO, the following was identified:
      i. The thermostats controlling the heat in each of the patients rooms within the unit were not secured in a fashion to prevent the patient from removing it and use it as a weapon or cause harm to themselves;

      ii. The unit manager failed to provide documentation to indicate the formal education that was given to each staff member working within the unit as to their duties in conducting daily / 15 minute environmental safety rounds per shift;

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

- The thermostats were immediately covered with ligature resistant covers, eliminating risk and approved by the DPH surveyor on 2/14/2018.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

- Staff were educated via electronic modules regarding environmental risk by 2/28/18.
- A read and sign education provided to all staff prior to taking work assignment for unit environmental safety checks daily and every 15 minutes-completed by 3/3/18.

(2) The date each such corrective measure or change by the institution is effective.
- See above date.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.
- Twice yearly EOC rounds with an interdisciplinary team will be completed to identify risks.-Ongoing.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.
- Manager, Behavioral Health
- Manager, Facilities

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1) and/or (2) and/or (i) General (6) and/or (l) Infection Control (1).

4. *Based on observation, review of facility documentation, and interview, the hospital failed to ensure that staff recognized and addressed infection control concerns in the intravenous (IV) mixing room during daily and/or terminal cleaning. The finding includes the following:
   a. On 4/3/18 at 10:55 AM during a tour of the pharmacy with the Director of Engineering, Pharmacy Interim Manager and Hospital CEO, two (2) Velcro strips were observed adhered to the biological safety cabinet (BSC). In addition, debris was observed inside the vent that was attached to the top of the BSC.

      Review of the cleaning logs during the period of 2/15/18 through 4/2/18 identified that numerous pharmacy staff performed daily cleaning of the sink, hoods, surfaces (tables, carts, sills, and ledges), chemo hood tray, and floors.

      Review of the terminal cleaning logs dated 3/12/18, 3/20/18, and 4/2/18 identified that contracted service #1 mopped and sanitized ceilings and walls, clean and sanitized designated surfaces including benches, carts, and hoods, doors, glass, and the exterior of equipment located in the ante and chemo rooms.

      Although staff were educated on the revised cleaning policy on 2/15/18, the aforementioned concerns were not addressed during daily and/or terminal cleaning.

      Interview with the Interim Pharmacy Manager and the Director of Engineering on 3/3/18 at 11:15 AM stated that the Velcro should have been removed from the BSC as it was not able to be effectively sanitized and were unable to identify where the debris noted in the vent came from and/or why staff didn't identify this concern.

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Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

- Velcro found on revisit 4/3/2018 was removed followed by cleaning with peridox and sterile alcohol on the same day. Also debris was removed from the exhaust transition with a HEPA filtered vacuum on 4/3/2018.

(2) The date each such corrective measure or change by the institution is effective.

- 4/3/2018

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.

- Twice yearly EOC rounds with an interdisciplinary team will be completed to identify risks.-Ongoing.
- Monthly rounding will be performed by the Director of Facilities and Engineering/Designee and the Interim Pharmacy Manager/Designee monthly to inspect for any deficiencies effective 2/15/2018.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.

- Vice President, Medical Affairs

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (i) General (6) and/or (l) Infection Control (1).

5. Based on observation, review of hospital policies and procedures and interviews for the out-patient rehabilitation center, the hospital failed to ensure that the environment and/or equipment was clean and/or properly maintained to ensure patient and staff safety. The findings include:
   a. Tour of the out-patient rehabilitation center on 12/18/17 at 9:30 AM with Physical Therapist #1 identified that a stainless steel handwashing sink was recessed into a counter. The counter edging was dislodged from the counter creating a loose piece of hard plastic that projected from the front of the counter top. The piece had shard edges and created a safety hazard for potential skin tears, bruising, and/or lacerations.

      At 9:45 AM observation of the hydroculator tank identified an accumulation of unidentifiable particles in the water and on the edges of the inside of the tank. Interview with PT #1 identified that it was hospital policy that environmental services cleaned the tank every two weeks.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

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- The stainless steel sink was repaired via plastic edging repair on 12/19/17.
- They hydrocollater was replaced on 3/31/2018 to the accumulation of particles in water. There has been no accumulation in the water.

(2) The date each such corrective measure or change by the institution is effective.
- See the dates above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.
- Physical Therapy Department staff is cleaning hydrocollator biweekly and documenting it in checklist. Ongoing.
- Environmental rounds will be done twice per year by the interdisciplinary team including the review of the hydrcollator and safety hazards.-Ongoing.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.
- Department Manager, Rehabilitation Services

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (i) General (6) and/or (l) Infection control.

6. Based on observation and review of hospital documentation at the Wound Center, the hospital failed to ensure that documentation was complete and accurate. The findings include:
   a. Tour of the Wound Center with the Program Director and review of cleaning logs for two hyperbaric chambers on 12/20/17 at 10:00 AM identified that the Chamber daily Start Up and Shutdown Checklist for Chamber #2 for the time period of June 19, 2017 through June 23, 2017 was incomplete. Review of the check list with the Clinical Manager at 10:05 AM identified that the hyperbaric technician requires further oversight to ensure complete and accurate documentation. Interview with the Hyperbaric Technician on 12/20/17 at 1:00 PM identified that, although it was his/her practice to review the check list to ensure all areas were complete, that task must have been over looked.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:
- The employee was reeducated immediately regarding checks of HBO on 12/20/2017, and the importance of completing the checks and documentation.
- Program Director or designee has conducted a daily review of Chamber daily start up and shutdown checklist (HBO checklist) since 12/20/2017.
- Results reported to the Vice President, Medical Affairs and to Organizational Performance Improvement and Safety Committee (OPSIC).

(2) The date each such corrective measure or change by the institution is effective.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

- 12/20/2017

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.
- Effective date of corrective measure audits done at 100% compliance for complete and accurate documentation and initialed for a six month period from 12/20/2017-5/20/2018.
- An interdisciplinary monitoring team who will continue to review the log when conducting twice-yearly environment of rounds.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.
- Program Director, Advanced Wound Center

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medial staff (2)(B) and/or (d) Medical records (3) and/or (d)(8).

7. Based on review of the clinical record for one patient who required transfer to a higher level of care for treatment of preterm labor and potential delivery, Patient #5, the hospital failed to ensure that the patient signed consent for transfer and/or that the patient participated in discussion of the risk/benefits of the transport. The findings include:
   a. Patient #5 arrived at the ED on 3/3/16 at 3:18 AM and reported that he/she had been diagnosed with strep throat and had received one dose of Amoxicillin. At 3:31 AM, MD #3 documented the patient's chief complaint as suprapubic pain, intermittently since the previous evening with light vaginal bleeding. The patient reported that she was sixteen weeks pregnant. MD #3 contacted the obstetrician/gynecologist (OB/GYN) on call who directed that the patient should go to Acute Care Hospital #1 if the pain persisted. Additional documentation identified that Patient #5 had called the on call OB/GYN, herself, three times in the last twenty four hours and received the same advice.

      A physical exam identified that the patient was anxious but not toxic appearing and a genitourinary exam identified clear, brownish vaginal discharge with a closed cervical os. A urinary tract infection (UTI) was suspected. An ultrasound performed at 3:34 AM identified a fetus with gestational age of sixteen weeks and one day with positive movement, no free fluid, no intrauterine hemorrhage with the cervix dialated approximately 3.5 cm. MD #3 documented that, given the appearance of the fetus, he/she did not suspect active miscarriage or placental abruption at this time. MD #3 consulted with an on call OB/GYN who advised treatment for the UTI and regular follow-up unless pain intensifies or patient had the onset of active bleeding. At 5:00 AM Patient #5 experienced active bleeding and MD #3 arranged for the patient to be evaluated by an OG/GYN, MD #7 in the ED. At 5:19 AM, Patient #5 was evaluated by MD #7 who identified that the patient did potentially have preterm labor or an impending placental rupture. MD #3 and MD #7 again, consulted with the OB/GYN at Acute Care Hospital #1 with the recommendation that Patient #5 be transferred to that hospital for further evaluation and potential emergent intervention. Report was called to

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Acute Care Hospital #1 by RN #4 at 5:55 AM and the patient was transported by paramedics at 6:06 AM. Review of an Emergency Transfer Documentation Checklist identified the patient's name, medical record number, date of birth, reason for transfer, (level of care needed not available at the current hospital), name of receiving hospital, name of provider accepting patient, information communicated to the accepting provider, medical control responsibility during transfer, information that the patient had been informed of the reason for transfer, and provider completing the checklist. However, the checklist lacked a signature. Additionally, the medical record contained a Request and Consent Transfer Form that included the patient's name, date of birth, medical record number and date and time. The document identified that the patient had been informed by MD #3 of the reason for transfer, risks involved and consented The document was not signed or dated by the patient or other responsible party. Review of the clinical record lacked documentation that the patient and/or spouse were involved with the decision-making process regarding the patient's condition and/or the need for emergent transport.

Interview with the Chief for the OB/GYN program, MD #7, on 12/19/17 at 8:30 AM identified that MD #3 did explain the risks and benefits of transfer to the patient and obtained consent, and that a signed copy of the consent should have been in the patient's chart.

Review of Patient #5's Hospital #2 discharge clinical record identified the patient was treated for pre-term premature rupture of membranes likely caused by chorioamniotis significant UTI.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

- Email to all providers by ED Medical Director identifying requirements for a transfer and policy on 6/13/2018.
- Transfer policy and requirements discussed in ED provider meeting on 6/14/2018.

(2) The date each such corrective measure or change by the institution is effective.

- See dates above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.

- Audit 10 transfers per month from January 1 to March 31 for 3 months of 95% compliance over 3 months for completion of transfer document, patient signature, and spouse involved with decision-making documented in chart.
- All finding are reported up through Operational Performance Improvement Committee.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.

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THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

- Medical Director, Emergency Department.

The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing service (1).

8. *Based on clinical record review, observations, facility documentation and interviews for one of three sampled patients who underwent a surgical procedure (Patient #2), the hospital failed to ensure surgical sponge counts were conducted according to hospital policy resulting in a retained sponge. The findings include:
   a. Patient #2 was admitted on 4/7/17 with a diagnosis of acute appendicitis and underwent an appendectomy on 4/8/17.

      Review of the clinical record identified the final instrument and surgical counts were correct and that Patient #2 was transferred to the recovery room at 9:05 AM. Further review of the clinical record identified another sponge count was performed which was not correct resulting in physician notification and an x-ray. The operative note dated 4/8/17 at 11:55 AM identified Patient #2 returned to the operating room subsequent to a post-operative abdominal x-ray reporting a retained sponge within the peritoneal cavity. Patient #2 underwent removal of a surgical sponge that was located in the subcutaneous tissues. Patient #2 was discharged on 4/9/17.
      In an interview on 12/18/17 at 3:00 PM, RN #2 identified the first surgical count included instruments, sponges and sharps upon closure of the peritoneum layer and the final count included sponges and sharps were both correct and acknowledged by the surgeon (MD #4). RN #2 further identified while the dressing was applied to the incision, CST#1 indicated that a surgical sponge could not be located. RN #2 identified that MD #4 was present, notified of the missing sponge and then left the operating room. RN #2 stated Patient #2 was being extubated while a search for the sponge was being conducted and then transferred to the recovery room area.
      In an interview on 12/19/17 at 11:35 AM, MD #4 identified he was informed that a count was correct when closing the fascia layer and could not recall being present in the room during the final count. MD #4 further identified he was in the recovery room when RN #2 informed him that the final count was not correct and a sponge could not be located therefore he ordered an abdominal x-ray. MD #4 identified the patient was returned to the operating room as a result of the abdominal x-ray report and upon opening the skin incision the sponge was located in the subcutaneous layer.
      In an interview on 12/20/17 at 1:00 PM, CST #1 identified the first surgical count occurs with initial closing and the second count occurs upon skin closure. CST #1 described during the case of Patient #2 the first count occurred during closure of the cavity and everything was correct i.e. sharps, instruments and sponges and acknowledged by MD #4. CST #1 identified the final count occurred during skin closure which included sponge and sharps, recalled that RN# 2 stated out loud the count was correct and that MD #4 acknowledged this. CST #1 recalled he did an independent count while the dressing was being applied and identified that a surgical sponge was missing of which he notified the surgical team. CST #1 further identified MD #4 ordered an x-ray and

then left the room.
Review of the hospital's Prevention of Retained Surgical Items policy identifies in part that sponge counts are performed before the start of the procedure, before closure of each body cavity and at skin closure.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

- Review procedure of instrument count during procedures, specifically the order in which fields are counted. Education and training on the importance of utilizing "stop the line" moments such as a wrong instrument count. Completed 4/9/2017.
- Education and training on the responsibility of the surgical team, provider included, on the policy and procedure surrounding instrument count, and what to do in the case of an off-count; Staff Education completed on 4/9/2017.
- Adoption of Saint Francis instrument count policy; to be completed by 6/1/2017.
- Education and training on the importance of utilizing "stop the line" moments such as a wrong instrument count – completed 4/9/2017.
- Educate and reinforce the culture of high reliability, specifically in the operating room where every staff member is part of the surgical team, and every member is responsible for patient safety in order to work toward a culture of support staff being able to voice concerns with providers; Staff Education Completed 4/9/2017.
- Validation of pre-procedural count will be done with Surgical Scrub and Circulator; verifying count noted is valid.
- Circulator will lead count, following the count sheet in order.

(2) The date each such corrective measure or change by the institution is effective.

- See dates above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.

- Adult of pre-procedural count and post-procedural count will be done by the Nurse Manager or his/her designee, ten (10) times a month to validate full compliance with policy starting on May 1, 2017 for 4 months.
- All finding are reported up through Operational Performance Improvement Committee.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.

- Manager, Perioperative Department

The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (a) Physical plant and/or (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing service (1).

9. *Based on clinical record review, observations, facility documentation and interviews for one of three sampled patients who underwent a surgical procedure (Patient #1), the hospital failed to

ensure the surgical site was identified according to hospital policy resulting in wrong site surgery. The findings include:

a. Patient #1 was admitted on 10/16/17 for right knee arthroscopy.
The operative note dated 10/16/17 identified pre-operative diagnosis of right knee torn lateral meniscus. The note further identified the procedure performed was a left diagnostic arthroscopy, wrong side and incorrect procedure. Review of the note indicated Patient#1 was identified in the pre-operative holding area, the appropriate side of surgery i.e. right knee was signed and consent confirmed. The note identified after the patient was transported into the operating room and anesthetized, the incorrect side i.e. left leg was prepped and a tourniquet was applied. A timeout was performed at which time the left leg was stated to be the correct site and the procedure proceeded. The note identified the medial meniscus appeared normal and that there was no true meniscal tear. While Patient#1 was in PACU it was noted that the incorrect side had been operated on.
In an interview on 12/18/17 at 2:45pm, RN#2 identified she was assigned to Patient#1's procedure and that she had encountered the patient in the pre-operative area. RN #2 identified she validated the patient's name, identification bracelet and consent but was not present when the surgeon marked the leg. RN#2 identified she had placed the tourniquet after identifying the mark on the patient's thigh and proceeded to prep the knee. RN#2 further identified a timeout was performed and recalled all staff present verbalized all was correct.
In an interview on 12/19/17 at 9:40AM, MD#5 identified he met with Patient#1 in the pre-operative area, reviewed the consent and identified the surgical site by initialing the right knee. MD#5 identified a time out was performed in the operating room after the circulating nurse prepped the leg, this would include referring to the computer screen for the surgical procedure and that everybody is expected to respond to confirm the time out. MD#5 further identified he was notified of the wrong surgical site by the PACU nurse.
Review of the facility policy titled Verification of Surgical Site identified in part all surgical cases involving right/left distinction will be marked prior to transport into the OR by surgeon. After the verification process has been completed, the operating physician will distinguish the correct surgical site by marking his/her initials as close as possible to the surgical incision. In addition, the Circulator will confirm the surgical site using patient's consent form and operating room schedule.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:

- Revision of Verification of Surgical Site policy to include but not limited to, more prescriptive active participation during Time Out from all members of surgical team including surgical staff and LIPs, repeat back confirmation of patient/surgical information. ** New Policy to be called "Universal Protocol" – completed and approved by perioperative committee 11/21/2017.
- Pre-procedural verification to include pre-op nurse and circulating RN at minimum.

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Completed and approved by PeriOp Committee 11/21/2017.

- Yearly review of the **New Policy to be called "Universal Protocol" for all OR staff and LIP.
- Education on revised policy – "Universal Protocol" for OR staff, LIP to be completed by 11/30/2017.
- Immediate High Reliability training for all pre-operative and surgical staff. JMH – 11/6/2017 and JSC – 11/13/2017.
- The following executive sessions were / will be held.
  - 10/31/2017 – Special Peri-operative meeting held at 6:30 a.m.
  - 11/1/2017 – Executive session to be held at PQIC at 7:00 a.m.
  - 11/8/2017 – Executive session to be held at MEC at 7:30 a.m.
  - 11/21/2017 – Executive session to be held at QCOB at 7:30 a.m.
- Hospital wide education on "Universal Protocol" to be completed by 12/31/2017.

(2) The date each such corrective measure or change by the institution is effective.

- See dates above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.

- Auditing 10 time outs per week to ensure consistency and compliance with "Universal Protocol Policy." Audits will continue until 100% compliance is reached for four consecutive months
- Reported monthly to Perioperative Committee and the Organization Performance Improvement and Safety Committee (OPISC).

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.

- Perioperative Manager

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (f) Diagnostic and therapeutic facilities.

10. Based on facility documentation and interviews for patients reviewed who underwent a nuclear medicine procedure, the hospital failed to ensure staff who prepared the egg product for the diagnostic study was appropriately trained and/or competent. The findings include:
    a. Observation of the nuclear med department on 12/20/17 failed to identify egg products stored in the department.
    In an interview on 12/20/17 at 9:00 AM, the Nuclear Medical Technician identified the test for the gastric emptying scintigraphy consists of eating a meal containing egg white. The Nuclear Medical Technician identified a radioactive tracer is added to a liquid egg product e.g. Egg beaters and microwaved for one minute until solid, the liquid egg product will be stored in the refrigerator labeled for patient use only. The Nuclear Medical Technician identified raw eggs are never used for the meal preparation. The Nuclear Med Tech further identified he completed the food handler training course on

12/10/17 and did not have any formal training prior to that date.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:
- Both food handlers completed a food handling training course on 12/10/2017.
- Certification is due to be renewed on 12/9/2020
- All patient food products were separated into a second refrigerator on 12/20/2017.

(2) The date each such corrective measure or change by the institution is effective.
- See dates above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.
- Any new staff member hired will be sent to the Food Handling Training Course.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.
- Radiology Department Manager

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D (b) Administration (2) and/or (e) Nursing service (1).

11. Based on observations, facility documentation and interviews the hospital failed to ensure that the surgical sterile field was not left unattended according to hospital policy. The findings include:
    a. During tour of the operating room with the O.R nurse manager on 12/18/17 at 10:00 AM it was identified that a surgical sterile table was set up in preparation for a case in operating room #3. Observation of the room failed to identify a staff member was present.
    In an interview on 12/18/17 at 10:10 AM, RN #3 identified that the CST had left the room and that she had intended to stay but left the room to gather additional equipment for the procedure.
    According to the AORN standards the sterile field is subject to unrecognized contamination and once created should not be left unattended since observation increases the likelihood of detecting a breach in sterility.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:
- All OR staff will be educated on the standard of care set forth by AORN on aseptic technique to be completed by 6/29/2018.
- Aseptic technique policy implemented 12/2017.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

- Aseptic technique policy reviewed with staff on 6/15/2018.
- Report to OPSIC (Organizational Performance and Safety Improvement Committee)

(2) The date each such corrective measure or change by the institution is effective.
- See dates above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.
- Audits will be performed on 5 cases per week for the compliance of the policy on Aseptic technique for two months at 100%. If not at 100%, audits will continue.
- All finding are reported up through Operational Performance Improvement Committee and Perioperative Committee.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.
- Manager, Perioperative Services

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D (i) General (6).

12. Based on observation, interviews and department documentation reviews, the hospital failed to ensure that safety precautions were maintained in the radiology department. The findings include:
    a. On December 19th 2017, staff from the Connecticut Department of Energy and Environmental Protection's (CTDEEP), Radiation Division, inspected Johnson Memorial Hospital as part of the Connecticut Department of Public Health's State Licensure inspection process. The scope of the DEEP inspection was to review Johnson Memorial Hospital's compliance with DEEP's Administrative Regulations Section 19-24-1 through 19-24-14 and 19-25-A1-A5, 19-25-D-1 through D-11 and the CT Public Health Code.

    The inspection consisted of observations, interview of hospital staff, an interview of the Chairman of the Radiation Safety Committee and a review of documents pertinent to the radiation protection program of Johnson Memorial Hospital.
    Within the inspection the following violation was noted:
    Section 19-24-8 "Radiation Information Labeling" states:

    Each area or room in which sources of ionizing radiation other than radioactive materials are used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and appropriate wording to designate the nature of the source or sources of ionizing radiation (example below)

    CAUTION * X-RAY
    Additionally, section 19-24-8 also states: **CAUTION * RADIATION AREA**

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This provision shall not apply to areas or rooms where x-ray equipment is used solely for diagnostic purposes by or under the direction of a healing arts practitioner as authorized by law"
Contrary to this, X-Ray room's number one, three and the CAT scan suite, which utilize X-Ray devices were posted "Caution Radiation Area". Additionally, not all entrances to these rooms were posted with caution signs.

Response:

(1) The measure that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance:
- All required signs were posted on day of visit (12/20/2017).

(2) The date each such corrective measure or change by the institution is effective.
- See date above.

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained.
- The manager will review the integrity and presence and the integrity of the signs when on daily rounds.

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with this plan of correction.
- Manager, Radiology Department

Respectfully submitted,

Stuart E. Rosenberg, M.B.A.
President